REMARKS

Following entry of this amendment, claims 1-17 will be pending in this application. Claims 1, 3 and 4 are currently amended, and new claims 12-17 are added. Support for the amendments and new claims can be found throughout the application as filed, e.g., at page 4, lines 14-16; page 7, lines 20-29; page 8, lines 36, to page 9, line 2; page 9, line 28, to page 10, line 6; and page 13, line 11, to page 14, line 20. No new matter has been added.

Restriction Requirement

Claims 2 and 6-8 were withdrawn by the Examiner as drawn to nonelected inventions. The previous Office action asserted that claim 1 does not contribute a special technical feature over the alleged prior art publication Kanato et al., 2005, Biochem. Biopys. Res. Commun., 326:836-843 ("Kanato"). However, as noted previously, Kanato is not prior art against the pending claims. Applicants inadvertently failed to include a translation of the Japanese language priority document with the last reply. Applicants submit herewith a translation of the Japanese language priority document for this application, Japanese Patent Application Serial No. 2004-096744. The priority document was filed on March 29, 2004, and therefore antedates the 2005 publication by Kanato. Applicants request acknowledgment of the perfection of the priority claim and withdrawal of the restriction requirement.

35 USC § 112, second paragraph

Claims 1, 3, 4, and 9-11 were rejected as allegedly incomplete for omitting a resolution step. Applicants do not agree with the rejection. However, applicants have amended claim 1 to recite that the cell is separated from the cell population if expression of the WT1 gene is detected. Applicants therefore request withdrawal of the rejection.

35 USC § 102

Claims 1, 3-5, and 9-11 were rejected under 35 USC § 102(a) as being anticipated by Kanato or Fraizer et al., 1995, Blood, 86:4704-06 ("Fraizer").

As noted above, applicants submit herewith a translation of the Japanese language priority document, which was filed on March 29, 2004, and therefore antedates the 2005 publication by Kanato. Applicants therefore request withdrawal of the rejection of the claims as allegedly anticipated by Kanato.

Applicants respectfully traverse the rejection of the claims in view of Fraizer. To anticipate a claim, a reference must disclose every limitation of the claim. Fraizer discloses separation of bone marrow precursor cells by FACS based on expression of CD34 and subsequent detection of WT1 expression in the cells so separated (p. 4704, right column). Fraizer does not teach or suggest detecting the expression of a WT1 gene in a cell in a cell population and separating the cell from the cell population if expression of the WT1 gene was is detected. Further, Fraizer does not teach or suggest the use of a reporter gene, detection of WT1 expression in a viable cell, or the expression quantities recited in claim 12. Therefore, Fraizer does not disclose the subject matter of the claims, and applicants request withdrawal of the rejection for alleged anticipation.

Claims 1, 3-5, and 9-11 were rejected under 35 USC § 102(b) as allegedly being anticipated by WO 97/39354; Menssen et al., 1997, Blood, 89:3486-93 ("Menssen"); Baird et al., 1997, Exp. Hematol., 13:1311-12 ("Baird"); Loeb et al., 2003, Leukemia, 17:965-971 ("Loeb"); or Tsuboi et al., Leukemia Res., 1999, 23:499-505 ("Tsuboi"). Applicants respectfully traverse the rejections.

WO 97/39354 discloses:

> a method of testing a graft material tissue for bone marrow or peripheral blood stem cell transplantation which comprises determining the level of expression of WT1 gene in a $CD34^-$ cell fraction of the tissue to detect leukemic cells and solid cancer cells in the tissue (abstract).

Based on this disclosure, it is clear that the separation (fractionation) of the cells is based on expression of CD34, not on WT1. WO 97/39354 does not teach or suggest detecting the expression of a WT1 gene in a cell in a cell population and separating the cell from the cell population if expression of the WT1 gene was is detected. Further, WO 97/39354 does not teach

or suggest the use of a reporter gene, detection of WT1 expression in a viable cell, or the expression quantities recited in claim 12. Therefore, WO 97/39354 does not disclose the subject matter of the claims, and applicants request withdrawal of the rejection for alleged anticipation.

Menssen discloses seeding of blood mononuclear cells onto agar plates and detection of WT1 gene expression in the resulting colonies by RT-PCR (p. 3486, left column). Menssen does not teach or suggest detecting the expression of a WT1 gene in a cell in a cell population and separating the cell from the cell population if expression of the WT1 gene was is detected. Further, Menssen does not teach or suggest the use of a reporter gene, detection of WT1 expression in a viable cell, or the expression quantities recited in claim 12. Therefore, Menssen does not disclose the subject matter of the claims, and applicants request withdrawal of the rejection for alleged anticipation.

Baird discloses isolation of $CD34^+$, $CD34^-$, and BMMNC cells using immunomagnetic beads followed by FACS (p. 314, right column) and sorting of cells into $CD34^+CD38^{-/lo}$ and $CD34^+CD38^{+/bright}$ populations by FACS (p. 315, right column). WT1 expression was then measured in the resulting populations using RT-PCR or immunohistochemistry in fixed cells. Baird does not teach or suggest detecting the expression of a WT1 gene in a cell in a cell population and separating the cell from the cell population if expression of the WT1 gene was is detected. Further, Baird does not teach or suggest the use of a reporter gene, detection of WT1 expression in a viable cell, or the expression quantities recited in claim 12. Therefore, Baird does not disclose the subject matter of the claims, and applicants request withdrawal of the rejection for alleged anticipation.

Loeb discloses transfection of 32D cl3 cells with a plasmid expressing a WT1 isoform lacking both exon 5 and the KTS insert (designated WT1 (–/–)) under the zinc-inducible metallothionein (MT) promoter (p. 965, right column). WT1 expression was measured in the cells by western blotting, RT-PCR, and northern blotting (p. 965-966). Flow cytometry was used to detect expression of Gr-1 (a marker of mature cells) (Fig. 4) and for cell cycle analysis using Hoechst 33258 staining (Table 2). Loeb does not teach or suggest detecting the expression of a WT1 gene in a cell in a cell population and separating the cell from the cell population if

expression of the WT1 gene was is detected. Further, Loeb does not teach or suggest the use of a reporter gene, detection of WT1 expression in a viable cell, or the expression quantities recited in claim 12. Therefore, Loeb does not disclose the subject matter of the claims, and applicants request withdrawal of the rejection for alleged anticipation.

Tsuboi discloses detection of differentiation markers Gr-1 and Mac-1 in cells constitutively expressing the WT1 gene (p. 502, left column). Tsuboi does not teach or suggest detecting the expression of a WT1 gene in a cell in a cell population and separating the cell from the cell population if expression of the WT1 gene was is detected. Further, Tsuboi does not teach or suggest the use of a reporter gene, detection of WT1 expression in a viable cell, or the expression quantities recited in claim 12. Therefore, Tsuboi does not disclose the subject matter of the claims, and applicants request withdrawal of the rejection for alleged anticipation.

CONCLUSION

Applicants submit that the pending claims are allowable and request early and favorable action thereon.

This reply is being submitted with a Petition for Extension of Time and the required fee. Please apply any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 14875-0170US1.

Respectfully submitted,

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